



K 954205

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### 510(k) SUMMARY

Contact/Submitter: Jodi Locher, Manager, Regulatory Affairs  
Date Prepared: August 29, 1995  
Trade Name: Amplatz Thrombectomy Device  
Common Name: Thrombectomy Catheter  
Classification Name: Percutaneous Catheter (per 21 CFR 870.1250)

Predicate Devices: Fogarty Arterial Embolectomy Catheters (pre-amendment)

Device Description: The Amplatz Thrombectomy Device is a polyurethane catheter that contains a distal rotor housing in which a small diameter, recessed impeller is attached to a drive shaft. The shaft is connected to a disposable, high-speed, air-driven motor. An infusion line with luer connector, attached to the proximal casing, allows infusion of saline, contrast medium, or thrombolytic medications.

Intended Use: The Amplatz Thrombectomy Device is intended for mechanical dissolution of acute and subacute thrombus in dialysis fistulae. This device is not intended to be used for the removal of atheroma and is contraindicated in coronary, cerebral, and pulmonary vessels.

Comparative Analysis: It has been demonstrated (through clinical studies) that the ATD is as safe and effective as surgery for the removal of acute and subacute thrombus within dialysis fistulae

Functional/Safety Testing: The Amplatz Thrombectomy Device has successfully undergone design validation, animal, and clinical testing.

Conclusion: The Amplatz Thrombectomy Device is substantially equivalent to the predicate device based on the results of laboratory, animal and clinical testing.